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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,661	09/06/2006	Andrew Michael Lindsay Lever	6947-73323-01	3959
24197	7590	08/26/2011	EXAMINER	
KLARQUIST SPARKMAN, LLP			MARVICH, MARIA	
121 SW SALMON STREET			ART UNIT	PAPER NUMBER
SUITE 1600			1633	
PORTLAND, OR 97204			NOTIFICATION DATE	DELIVERY MODE
			08/26/2011	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/567,661	<b>Applicant(s)</b> LEVER ET AL.
	<b>Examiner</b> MARIA MARVICH	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 30 December 2010.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5)  Claim(s) 49 and 50 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 49 and 50 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on 08 February 2006 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/10 has been entered. Claim 49 and 50 are pending.

### ***Claim Objections***

Claim 49 is objected to because of the following informalities: In claim 49 several informalities require amendment in order to provide accuracy and clarity. For clarity, line 2 should be amended to indicate, --the method comprising:--.

In line 9, “said SIV Gag-Pol” does not accurately reflect the recitation in line 8 especially as use of the term “said” means that the limitation that follows must be recited exactly as previously recited. In this case, the claim is drawn to “one or more Simian Immunodeficiency Virus (SIV) Gag-Pol nucleic acid sequences”. Hence, in line 9, it is not clear if all or one of these one or more sequences are described. The recitation of “one or more” does not actually seem necessary in the claim. First, the claim recites the presence of a Gag-Pol sequence and it is not clear why there should be more than one. Secondly, recitation that the cell “comprises” this sequence is enough to allow for more than one copy of the Gag-Pol sequence.

Finally, in claim 1 to clarify that cell comprises the vector, it would be preferable to recite in line 12, --wherein the cell further comprises a vector--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of expressing a therapeutic or antigenic protein or peptide to an individual, the method comprising administering to the individual an effective amount of a chimeric virus comprising a heterologous nucleic acid sequence encoding the therapeutic or the antigenic protein or peptide wherein the nucleic acid sequence is under control of an expression control sequence or a pharmaceutical composition thereof, wherein the chimaeric virus is produced by a method comprising culturing a host cell which comprises 1) a Simian Immunodeficiency Virus (SIV) Gag-Pol nucleic acid sequence under control of an expression control sequence wherein the SIV Gag-Pol nucleic acid sequence encodes an SIV capsid, 2) a vector comprising a Human Immunodeficiency Virus type 2 (HIV-2) packaging signal and the heterologous nucleic acid sequence and 3) SIV accessory genes necessary for viral assembly and 4) an envelope coding sequence under control of expression control sequences wherein said culturing results in production of the chimaeric virus which comprises the vector packaging within the SIV capsid, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This is a new rejection.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter., 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The method as recited is drawn to a method of delivering a therapeutic or an antigenic protein or peptide to an individual. However, the method actually involves delivering a chimaeric virus that comprises sequences encoding the protein or peptide. While some sequences may be expressed within the composition comprising the virus, the steps of delivering a chimaeric virus are not intended to deliver protein. Rather, once the virus is present in the individual the process of expression will begin and at this point, the protein/peptide will be present in the cell. Hence, the method as recited is not capable of delivering the protein or peptide to the individual.

Secondly, the method of preparing the virus requires only use of a vector encoding the therapeutic or the antigenic protein or peptide and a vector comprising SIV Gag-Pol sequences. From the art and the specification, it is clear that these sequences alone are insufficient to produce a virus. For example, the specification produced the chimeric virus by co-transfection of an SIV provirus, envelope coding sequences and the vector comprising the HIV-2 packaging sequences with the protein coding sequences. As well, White et al demonstrate related methods

for production of lentivirus and it is clear that more than just Gag-Pol and packaging sequences are required (see page 2833, col 2).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Primary Examiner  
Art Unit 1633

/Maria B Marvich/  
Primary Examiner, Art Unit 1633

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